

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MERCK EPROVA AG,

Plaintiff,

v.

BROOKSTONE PHARMACEUTICALS,
LLC a/k/a ACELLA PHARMACEUTICALS,
LLC, et al.

Defendants.

No. 1:09-CV-9684(RJS)(JCF)

DEFENDANTS' OBJECTIONS TO DIRECT TESTIMONY OF HAL PORET

Defendants, by and through counsel, submit the following evidentiary objections to the direct testimony affidavit of Hal Poret. (Plaintiff's Trial Exhibit No. 291). Defendants generally object to Mr. Poret's proffered testimony, because his testimony consistently uses the term "pure isomer" in place of the term "substantially pure isomer," which is the term his survey purportedly tested. Mr. Poret is not a chemist, physician, or pharmacist, and his testimony about the survey he conducted in this action should not be used to present non-expert testimony concerning chemical purity. As Mr. Poret acknowledges (Poret Trial Aff. at 32), and as the evidence will show (see, e.g., Butler Trial Aff. ¶ 25; Williams Trial Aff. ¶ 30; Katz Dep. 25, 214), the term "substantially pure" lacks precise or generally-understood meaning. Thus, Mr. Poret should not be permitted to bolster or attempt to change the results of his survey by using new, imprecise, and incorrect nomenclature in his trial affidavit. Accordingly, his testimony should be excluded or limited on the grounds that it states an improper opinion under Federal Rules of Evidence 702 and 703, lacks foundation and is not based on personal knowledge under Federal Rule of Evidence 602, is beyond the scope of his expertise and designation under Federal

Rule of Civil Procedure 26, is unfairly prejudicial, confusing, and misleading under Federal Rule of Evidence 403, and is vague.

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 1-2. “On the label and insert for the Brookstone PNV-DHA product, the “Folate” ingredient is described in parentheses as containing the following: • L-methylfolate as Xolafin 600 mcg • Folic acid, USP 400 mcg. I understand that for Brookstone’s other nutritional products, the “Folate” ingredient is described in a near identical manner. It is my understanding based on reviewing the Second and Third Amended Complaints and through discussions with counsel, physicians, and pharmacists, that methylfolate can occur in one of two forms (or diastereoisomers), the L-form or D-form. The letters “L” and “D” are used as conventions in the naming of chemicals to distinguish between these two diastereoisomers, which can have different properties. The L-form is the biologically active form of folate (naturally occurring in food and the human body) and the D-form is an unnatural form.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry, and is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	
	Cumulative (FRE 403)	
	Hearsay (FRE 802)	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 4. “Respondents in the Test Group were exposed to and questioned about the folate ingredient termed Xolafin, which is designated on the label and insert of Brookstone’s PNV-DHA product as “L-methylfolate.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Assumes facts not in evidence (that the folate ingredient is termed “Xolafin”)	
Pg. 6. “This was necessary given that the label and insert list a number of ingredients and it was critical to ensure that respondents were clear on the specific ingredient to which questions pertained.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (does not replicate market conditions) (FRE 702, 703)	Overruled ____
Pg. 7. “The purpose of this question was to determine the extent to which the L-methylfolate designation conveyed to respondents that Xolafin consists only (or substantially) of the L isomer (which would make it a “pure” L isomer).”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested “substantially pure,” not “pure,” and there is no accepted definition of “substantially pure”) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance “pure”)	
	Argumentative	
	Assumes facts not in evidence (that the folate ingredient is termed “Xolafin”)	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 8. “These questions allowed the survey to determine whether any perception that the ingredient <u>is</u> or is <u>not</u> a pure isomer was <u>caused</u> by the “L-methylfolate” designation.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested “substantially pure,” not “pure,” and there is no accepted definition of “substantially pure”) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance “pure”)	
	Argumentative Assumes facts not in evidence (that the folate ingredient is termed “Xolafin”)	
Pg. 8-9. “This eliminates the allegedly deceptive element by using a chemical name that communicates that the product consists of a mixture of both the D and L isomers....”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry, and is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	
	Beyond scope of affiant’s expertise	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 9-10. "45% of pharmacists in the Test Group answered that the Xolafin designated L-methylfolate is a pure isomer and only 9% answered that it is not. Screening out the respondents who did not refer to the "L" designation as their reason for believing it is a pure isomer leaves a net of 30% of pharmacists whose belief that Xolafin is a pure isomer was caused specifically to the use of the "L" designation."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure," and there is no accepted definition of "substantially pure") (FRE 702, 703)	Overruled ____
	Assumes facts not in evidence (that Xolafin is designated L-methylfolate)	
Pg. 10. "In the physician sample, 37% of the Test Group answered that the Xolafin designated L-methylfolate is a pure isomer and only 4% answered that it is not. Screening out the respondents who did not refer to the "L" designation as their reason for believing it is a pure isomer leaves a net of 24% of physicians whose belief that Xolafin is a pure isomer was caused by the use of the "L" designation."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure," and there is no accepted definition of "substantially pure") (FRE 702, 703)	Overruled ____
	Assumes facts not in evidence (that Xolafin is designated L-methylfolate)	
Pg. 11. "5) All of the above-cited net statistics are statistically significant at the 98% or 99% confidence levels."	Improper opinion, insufficient basis for opinion (improper to report confidence level for a non-probability sample) (FRE 702, 703)	Sustained ____
		Overruled ____

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 11. "It is my understanding that pharmacists are the primary source of concern, as pharmaceutical labels and inserts are most often reviewed by pharmacists. Physicians are also a source of concern as physicians may review the label and insert information relating to a product they are considering prescribing. The physician segment of the universe was limited to the following segments, which are the primary types of physicians that would prescribe pre-natal vitamins: (1) OB/GYNs and (2) Internal Medicine and General/Family Practice."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (affiant is not relying on another expert for these statements about pharmacists and physicians) (FRE 702, 703)	Overruled ____
	Affiant is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	
Pg. 12. "Organizations that put out pharmaceutical and healthcare products routinely rely on and make decisions of importance based on the results of online survey research among health care professionals."	Beyond the scope of affiant's expertise	
	Relevance (FRE 402)	Sustained ____
Pg. 12. "Online surveys are also commonly accepted in evidence in U.S. District Court proceedings."		Overruled ____
	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Argumentative	Overruled ____
	Legal conclusion	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 12. “An online survey was also appropriate here as the information from the product label and insert were easy to clearly present and read online, and health care professionals are accustomed to reviewing information about pharmaceutical products online.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Affiant is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	Overruled ____
	Argumentative	
	Legal conclusion	
Pg. 16. “...but gave answers relating to the specific form of the folate and/or the potential benefits of that formulation, which may related to the ‘L’ designation.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	
	Beyond the scope of affiant’s expertise	
Pg. 18. “In the Test Group, 45% of pharmacists (68 of 150) answered that the folate ingredient termed Xolafin is a substantially pure isomer and 9% (13 of 150) answered that it is <u>not</u> .	Vague as to “substantially pure”	Sustained ____
		Overruled ____

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 18. “The 45% result is an initial indication that there was a high level of mistaken belief that Xolafin is a substantially pure isomer. However, it is necessary to examine the subsequent answers explaining <u>why</u> respondents answered that it is a pure isomer. This enables us to determine how many respondents’ belief was directly <u>caused</u> by the “L” designation and to weed out any respondents who answered that it is a pure isomer for other reasons, such as other information, guessing, or a different understanding of what a “pure isomer” means.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance “pure”)	
	Argumentative Assumes facts not in evidence (that Xolafin is not a “substantially pure” isomer)	
Pg. 18, n. 12. “An additional five respondents did not mention the ‘L’ designation but referred to the name or form of the chemical, which may refer to the L designation.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26	
Pg. 19. “These verbatim responses make clear that the “L” designation was the reason that 30% of the pharmacists mistakenly believed that the Xolafin ingredient is a pure isomer. The other 15% who answered that Xolafin is a pure isomer may have done so for other reasons and are not counted in the estimate of the net misleading impact of the “L” designation. The 30% figure represents a high level of deception and far exceeds the 9% that answered that Xolafin is <u>not</u> a pure	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested “substantially pure,” not “pure”) (FRE 702, 703)	Overruled ____
	Assumes facts not in evidence (that Xolafin is not a “substantially pure” isomer)	
	Argumentative	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
isomer.”		
Pg. 20. “In the Control Group, 24% of pharmacists (36 of 150) answered that the folate ingredient termed Xolafin <u>is</u> a substantially pure isomer and 35% (53 of 150) answered that it is <u>not</u> . Of the 53 Control Group respondents who answered that the folate in Xolafin is <u>not</u> a substantially pure isomer, 43 (29% of all 150 Control Group respondents) gave open-ended answers when asked what made them think so that specified that it was the “D, L” designation that caused them to understand that Xolafin was <u>not</u> a pure isomer.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested “substantially pure,” not “pure”) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26	
Pg. 21. “These verbatim responses make clear that the ‘D,L’ designation communicated to 29% of the pharmacists in the Control Group that the Xolafin ingredient is not a pure isomer....The same conclusion is compelled by a comparison of Test and Control Group results for the closed-ended question regarding whether or not Xolafin is a pure isomer.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested “substantially pure,” not “pure”) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 21. "...a 'D,L' designation causes a substantial percentage of respondents to properly understand the folate content."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (affiant is not a pharmacist, physician, or chemist and cannot opine about "properly understood" meaning) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26 and cannot opine about "properly understood" meaning	
Pg. 22. "Respondents were far more likely to mistakenly believe the product is a pure isomer in the Test Group, by a margin of 21%. This difference is statistically significant at the 99% confidence level and is of a magnitude that represents a substantial rate of deception."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure") (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry under FRCP 26	
	Assumes facts not in evidence (that Xolafin is not a "substantially pure" isomer)	
	Argumentative	
	Legal conclusion/invades province of the Court	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 22. "This difference is also statistically significant at the 99% confidence level and is of a magnitude that represents a substantial increase in the ingredient being properly understood with the "D,L" designation. Since the only difference between the Test and Control Groups is the change from "L" to "D,L", it is clear that the use of the "L" designation has a meaningful tendency to mislead pharmacists into believing the Xolafin folate ingredient consists of a pure L isomer."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure") (FRE 702, 703)	Overruled ____
	Affiant not properly designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance "pure")	
	Argumentative	
Pg. 22. "It is also useful to consider the ratio of those pharmacists who believed Xolafin is a pure isomer to those who believed it is not a pure isomer...."	Lack of foundation and personal knowledge (FRE 602)	
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure") (FRE 702, 703)	
	Affiant not properly designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance "pure")	
	Argumentative	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 23. "...the overwhelming majority of those with an opinion (84%) who saw the L-designation believed it was a pure isomer whereas only a minority (40%) did in the Control Group."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure") (FRE 702, 703)	Overruled ____
	Argumentative	
Pg. 23. "...that the use of the "L" designation causes a substantial percentage of pharmacists to mistakenly believe that the Xolafin ingredient contains only the L isomer of folate."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure") (FRE 702, 703)	Overruled ____
	Affiant not properly designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance "pure")	
	Argumentative	
Pg. 23, n. 15. "The reason the percentage using the internal analysis (30%) is somewhat higher than using the Control Group (21%) is evident from review of the responses from Control Group respondents who answered that Xolafin is a substantially pure isomer even though the designation was 'D,L.' A number of Control respondents who answered that Xolafin is a pure isomer identified the 'D,L' designation as their reason for believing that Xolafin is a substantially pure isomer. Apparently, these respondents understood that the ingredient was a mixture of isomers but interpreted	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure"; further, affiant is clearly guessing how respondents interpreted the stimuli in order to draw a more favorable conclusion) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry, and is not a pharmacist or physician and is not designated as an expert on the knowledge,	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
<p>‘substantially pure isomer’ to include combinations of isomers and not to mean only a single isomer....</p> <p>Therefore it is my opinion that the 30% figure is a better estimate of the impact of the ‘L’ designation, whereas the 21% figure reflects that some pharmacists did not understand the term ‘pure isomer’ to mean only a single form.”</p>	<p>understanding, or practices of physicians or pharmacists under FRCP 26</p> <p>Speculation</p> <p>Argumentative</p>	
<p>Pg. 26. “The 37% result is an initial indication that there was a high level of mistaken belief that Xolafin is a substantially pure isomer.”</p>	<p>Argumentative</p> <p>Legal conclusion/invades province of the Court</p> <p>Vague as to “substantially pure”</p>	<p>Sustained ____</p> <p>Overruled ____</p>
<p>Pg. 26, n. 16. “An additional five respondents did not mention the ‘L’ designation but referred to the name or form of the chemical, which may refer to the L designation.”</p>	<p>Lack of foundation and personal knowledge (FRE 602)</p> <p>Improper opinion, insufficient basis for opinion (the affiant is clearly guessing how respondents interpreted the stimuli) (FRE 702, 703)</p> <p>Affiant is not designated as an expert on nomenclature or chemistry, and is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26</p> <p>Speculation</p> <p>Argumentative</p>	<p>Sustained ____</p> <p>Overruled ____</p>

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 27-28. "These verbatim responses make clear that the 'L' designation was the reason that 24% of the physicians mistakenly believed that the Xolafin ingredient is a pure isomer....These Test and Control verbatims show that the 'L' designation causes a substantial percentage of physicians to have a mistaken belief regarding the Xolafin folate content and that a 'D,L' designation causes a substantial percentage of respondents to properly understand the folate content."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (the survey tested "substantially pure," not "pure," and the affiant is improperly opining about which interpretation is correct and which is "mistaken," i.e. he is speaking for respondents rather than reporting results) (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on nomenclature or chemistry, and is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	
	Legal conclusion/invades province of the Court	
	Speculation	
Pg. 29. "Respondents were more likely to mistakenly believe the product is a pure isomer in the Test Group, by a margin of 11% (statistically significant at the 98% confidence level). Similarly, respondents were more likely to correctly understand that the product is <u>not</u> a pure isomer in the Control Group when the single "L" designation was not used, by a margin of 17% (statistically significant at the 99% confidence level)."	Argumentative	
	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Argumentative	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 30. "Although the majority of Control respondents with an opinion (55%) also answered that it was a pure isomer, the 35% difference must be attributable to the "L" designation and shows a large increase in the likelihood that physicians will mistakenly interpret the folate content when the "L" designation is used. Accordingly, while physicians were generally less likely to have any opinion about whether Xolafin is a pure isomer and were less sophisticated than pharmacists in understanding the chemical designations, they nevertheless were subject to a significantly increased tendency to misunderstand the content of Xolafin due to the "L" designation."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant not properly designated as an expert under FRCP 26 (including as to the sophistication of physicians as compared to pharmacists)	
	Argumentative	
Pg. 31. "Both methods of considering the data support the same conclusion – that the use of the "L" designation causes a substantial percentage of physicians to mistakenly believe that the Xolafin ingredient contains only the L isomer of folate."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant not properly designated as an expert on nomenclature or chemistry under FRCP 26 (affiant seeks to testify concerning what level of purity makes a substance "pure")	
	Argumentative	
Pg. 31. "This comment by Ms. Butler misses the point of these open ended questions and is logically flawed."	Argumentative	Sustained ____
		Overruled ____

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 32. "To exclude their closed ended answers on the basis of their initial open ended response is illogical and improper."	Argumentative	Sustained ____ Overruled ____
Pg. 32. "This analysis is simply illogical and wrong."	Argumentative	Sustained ____ Overruled ____
Pg. 32. "Moreover, to the extent there is any variation in people's understanding of substantially pure, the result of such variation is to <i>decrease</i> the rate of confusion and increase noise."	Lack of foundation and personal knowledge (FRE 602) Improper opinion, insufficient basis for opinion (FRE 702, 703)	Sustained ____ Overruled ____
Pg. 33. "And again, even if there was variation in interpreting the phrase substantially pure, all this does is increase noise and dilute the confusion response."	Lack of foundation and personal knowledge (FRE 602) Improper opinion, insufficient basis for opinion (FRE 702, 703)	Sustained ____ Overruled ____
Pg. 33. "Thus, the survey bends over backwards to ensure that the "I Don't Know" and "No Opinion" responses are taken into account."	Argumentative Lack of foundation and personal knowledge (FRE 602) Improper opinion, insufficient basis for opinion (FRE 702, 703)	Sustained ____ Overruled ____
Pgs. 33-34. "However, the verbatim analysis is strong and shows that the confusion numbers are dragged down over the word "substantially pure."	Argumentative Lack of foundation and personal knowledge (FRE 602) Improper opinion, insufficient basis for opinion (FRE 702, 703)	Sustained ____ Overruled ____

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pg. 34. “Ms. Butler also states that my control is unreliable. However, she never provides any reasoning for this statement.”	Argumentative	Sustained ____
		Overruled ____
Pg. 35. “However, analyzing only those with an opinion is informative.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Argumentative	
Pg. 36. “Given that they had already referred to the L-designation, they do not need to repeat that to be counted.”	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Argumentative	
Pg. 37. “Finally, Ms. Butler claims that there is missing data from the first question – she states that respondents either could not or were unwilling to answer. This is simply false.”	Argumentative	Sustained ____
		Overruled ____

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Pgs. 37-38. "Labels and package inserts specifically listing Xolafin-B as an ingredient were not included in the survey. However, I have reviewed the labels and package inserts of Acella products that indicate they contain Xolafin-B. In those labels and package inserts, the information conveyed is identical to those labels and inserts that claimed the use of Xolafin. The only distinction was the substitution of the term Xolafin-B for the term Xolafin.	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Affiant is not designated as an expert on labeling, and is not a pharmacist or physician and is not designated as an expert on the knowledge, understanding, or practices of physicians or pharmacists under FRCP 26	
I am advised by Merck's counsel that Xolafin-B is a fanciful term selected by Acella and that the "B" component of that term has no standard significance in the field of folate usage. Consequently the labels and package inserts that contain the term Xolafin-B convey the same information to prospective readers with regard to the nature of the purity of the ingredient in the products. As such, it is my opinion that the use of the term Xolafin-B would be perceived by pharmacists and physicians in the same manner as the term Xolafin.	Beyond scope of the disclosure and the affiant's stated opinions under FRCP 26, and beyond the scope of the affiant's expertise (as to the affiant's opinions concerning the information conveyed in labeling and what would be perceived by un-surveyed respondents (i.e., the affiant is submitting his own opinion for pharmacists and physicians he did not survey))	
	Hearsay (FRE 802)	
I do not have an opinion as to whether Xolafin-B is or is not 'substantially pure.' However, it is my opinion that a comparable number of pharmacists and physicians would have believed that Xolafin-B <u>was</u> pure or substantially pure as had that view with Xolafin."		

Respectfully submitted,

MILLER & MARTIN PLLC

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